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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,968	12/19/2001	Harry R. Howard JR.	PC11840A	4855

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/024,968

Applicant(s)

HOWARD, HARRY R.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 6-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5 and 19-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Detailed Action***

The following is responsive to the election received Oct. 4, 2004.

Applicant's election of the compound [2-(3,4-dichlorophenoxy)-5-fluorobenzyl]-methamphetamine as the "SRI anxiolytic or antidepressant" and a further election of species of L-phenylalanine with traverse is acknowledged.

However, since Applicant has not specifically pointed out the alleged errors in the requirement mailed Aug. 30, 2003, the requirement for election is maintained for reasons already of record.

Concerning the method claims, no prior art was found for the elected species, so the search was expanded to the non-elected species.

With respect to the composition claims, prior art on the elected species was found and a rejection based on the prior art is submitted below.

***Claim Objection(s)***

1. Claims 2, 3, 5, 21, 23-30 are objected to because of the following informalities: in claim 2, a —I— should be added next to the structural formula. In claim 2, line 17, "structure" should be deleted and replaced with —formula—. In claims 3, 5, line 1, "A compound" should be deleted and replaced with —A pharmaceutical composition—. In renumbered claim 21, line 1, "21" should be cancelled and replaced with —20—. In renumbered claim 23, line 1, "23" should be deleted and replaced with —22—. In renumbered claim 24, line 1, "23" should be deleted and replaced with —22—. In renumbered claim 25, line 1, "23" should be deleted and replaced with —22—. In renumbered claim 26, line 1, "23" should be deleted and replaced with —22—. In

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renumbered claim 27, line 1, "23" should be deleted and replaced with --22-. In renumbered claim 28, line 1, "23" should be deleted and replaced with --22-. In renumbered claim 29, line 1, "25" should be deleted and replaced with --24-. In renumbered claim 30, line 1, "24" should be deleted and replaced with --23--.

Appropriate correction is required.

***Claim Rejection(s)—35 USC 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 2, 3, 5, 19-21, 22-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 22, the limitation "other demyelinating conditions" renders the claims vague and indefinite. The specification does not clearly set forth explicitly and with reasonable clarity the definition of this limitation. Instead, the description at page 3, lines 11-12, "'other demyelinating conditions especially encephalomyelitis'" is merely exemplary and does not describe what would be excluded by the limitation.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all of the criteria for patentability and whether the

specification meets the criteria of 35 USC 112, first paragraph with respect to the claimed invention." Please see MPEP 2173.

Because the limitation is exemplary and does not depict what would be excluded, the Examiner respectfully submits that the metes and bounds of the patent protection desired are unclear, and one of ordinary skill in the art would not be reasonably apprised of the scope of the claimed method.

Additionally, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as", or the Examiner submits "especially" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1, 22 recite the broad recitation "other demyelinating diseases" and "peripheral neuropathy", and the claim also recites "especially" or "such as" and "encephalomyelitis" and "painful neuropathy" and "diabetic neuropathy" which is the narrower statement of the range/limitation.

Finally, regarding claims 2 and 23, the phrase "i.e." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Please see claim 2, lines 9-10; claim 23, lines 25-26.

***Claim Rejection(s)—35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1, 2, 3, 5, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard, Jr. et al., 6,677,378 (102(e)=02/1999) in view of Blum et al., 5,189,064.

Howard, Jr. et al. disclose a pharmaceutical composition for treating various conditions such as cocaine addiction, wherein the composition comprises an effective amount (0.01-10.0 mg/kg body weight) of a compound represented by Formula I. More specifically, the compound may be [2-(3,4-dichlorophenoxy)-5-fluorobenzyl]-

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methylamine or a pharmaceutically acceptable salt thereof. Please see the abstract; col. 1-col. 3, line 19; col. 6, lines 41-46; col. 20, lines 9-15; col. 39, line 43.

Howard, Jr. et al. do not disclose combining the compound with a neurotransmitter inducing or precursor agent such as L-phenylalanine, L-DOPA etc. However, the Examiner refers to Blum et al., which disclose compositions for treating cocaine addiction, the composition comprising a neurotransmitter synthesis-promoting precursor such as L-phenylalanine, L-DOPA, L-tyrosine or L-tryptophan. Please see the abstract; claim 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Howard, Jr. et al. by combining [2-(3,4-dichlorophenoxy)-5-fluorobenzyl]-methylamine with a neurotransmitter synthesis-promoting precursor such as L-phenylalanine, L-DOPA, L-tyrosine or L-tryptophan because one of ordinary skill in the art would reasonably expect the combined effects of the two compounds to effectively treat cocaine addiction. Such a modification would have been motivated by the reasonable expectation that the two compounds, through their respective mechanisms, would restore normal neurotransmitter function in the patient's brain thereby successfully treating cocaine addiction.

In addressing the claims drawn to dosages of neurotransmitter-inducing or precursor agent, since efficacy is dependent upon dosage amounts, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the compositions such that the precursor agent is present in amounts effective to treat cocaine addiction.

Finally with respect to the claimed intended use, the Examiner respectfully submits that intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, although the prior art composition is taught to treat cocaine addiction, there is no structural difference between the claimed composition and the composition of the prior art. Absent evidence to the contrary, the Examiner submits that the prior art composition would be capable of performing the claimed intended use.

#### ***Allowable Subject Matter***

Claims 22-30 are free from the prior art because the prior art does not disclose or fairly suggest Applicant's claimed method.

#### ***Conclusion***

Claims 1, 2, 3, 5, 19-21, 22-30 are rejected.

Claims 4, 6-18 are withdrawn from consideration.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM   
Jan. 24, 2005

  
Cybille Delacroix-Muirheid  
Patent Examiner Group 1600